PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Emotion Regulation Group Therapy for Deliberate Self-Harm: A Multi-Site Evaluation in Routine Care using an Uncontrolled Open Trial Design
AUTHORS	Sahlin, Hanna; Bjureberg, Johan; Gratz, Kim; Tull, Matthew; Hedman, Erik; Bjärehed, Jonas; Jokinen, Jussi; Lundh, Lars-Gunnar; Ljótsson, Brjánn; Hellner Gumpert, Clara

VERSION 1 - REVIEW

REVIEWER	Joel Paris McGill University Canada
REVIEW RETURNED	22-Feb-2017

GENERAL COMMENTS	Mental health clinicians now have therapeutic tools that are specific for patients with BPD, Emotion dysregulation (ED) is the core feature of BPD, and some have even suggested that the condition be renamed to emphasize this clinical presentation. The most effective treatment methods have targeted ED. Several of these methods, most particularly DBT, have a good evidence base for efficacy. However most currently available therapies are lengthy (at least a year), expensive, and not available in public settings (and if they are, waiting lists inevitably develop). There is a clear need for approaches that are brief, accessible, and effective. The method developed by Gratz and Roeme, emotion regulation group therapy (ERGT), focuses on ED, is group-based, and brief. This study demonstrates that ERGT is effective in a real world setting. Its methods and conclusions are convincing. Thus the paper makes a contribution to the BPD treatment literature. The authors could have presented an even strong case by pointing out the problems of inaccessibility for evidence-based treatments noted above. My one criticism is that the paper does not acknowledge that there are similar methods described in the literature that have undergone clinical trials. Most particularly, Systems Training for Emotional Predictability and Problem Solving (STEPPS(is almost identical to ERGT. Unfortunately, it is not in the reference list. It is important to know that different teams have independently developed different variations of the same approach. It is also important to acknowledge that one can take an integrative approach to BPD treatment, an avoid the “alphabet soup” of similar treatments, each with its own acronym.

REVIEWER	Kirsten Barnicot Imperial College London, United Kingdom
REVIEW RETURNED	13-Mar-2017

GENERAL COMMENTS	The study is important as it is one of the first to evaluate the feasibility and outcomes of Emotion Regulation Group Therapy in a real-world setting as opposed to a university-led efficacy trial. This intervention has shown positive effects for BPD and self-harm in efficacy trials and therefore evaluating it in a real-world setting is an important next step. Strengths of this research include the large sample size and multi-site real world study setting, increasing the potential for generalisability of the findings. The statistics also appear sound and the authors evaluate the effect of potentially confounding factors such as treatment site, and mechanistic factors such as treatment completion versus dropout. However, a major inaccuracy is the authors' use of the term "effectiveness trial" or "effectiveness study" to describe the research. The effectiveness of an intervention can only be determined using an RCT design with random allocation to intervention versus control groups, whereas this was an uncontrolled study evaluating change on the outcome measures pre and post-intervention. Any changes on the outcome measures cannot necessarily be attributed to the intervention and therefore the effectiveness of the intervention cannot be determined from this study. I would consider "real-world outcome study" to be a more accurate descriptor and would suggest the authors change this term throughout the paper (e.g, title, abstract, strengths + limitations, pg. 5 aims and design, discussion pg. 18 and any other places). Similarly there are several instances throughout the paper (e.g. abstract, page 22, any other places) where the authors conclude that their research has shown that ERGT is an "effective" intervention. I would disagree that this conclusion can be reached on the basis of the research, for the reasons outlined above. The study has shown that individuals receiving ERGT experience significant improvements on a number of outcomes by these cannot necessarily be attributed to ERGT. I would suggest the authors change statements on effectiveness throughout to avoid over-stating their findings. Pg. 5 the design is described as an "open trial design". It would be helpful to clarify that this was an "uncontrolled open trial" as open trials can be either controlled or uncontrolled. The exclusion of people with substance dependence should be justified, particularly in the context of a "real world" outcomes study, as in everyday clinical practice BPD and substance dependence are very common comorbidities, and so their exclusion may limit generalisability. Finally, the discussion of the superior outcomes in intervention completers attributes this entirely to the intervention - the authors should also highlight that intervention completers may have differed from dropouts in ways that predisposed them to better outcomes and hence their superior outcomes may not be attributable to the intervention.

REVIEWER	Hanga Galfalvy Columbia University, New York, NY, USA
REVIEW RETURNED	03-May-2017

GENERAL COMMENTS	Reviewer's Comments The article "Emotion Regulation Group Therapy for Deliberate Self-Harm: A Multi-Site Effectiveness Open Trial" describes a multi-site, single-group study of the effect of group therapy on self-harm frequency in patients with (sub-threshold or full) Borderline Personality Disorder, with no control group. There were also some secondary outcomes measures on quantitative scales. The Methods section states that out of 32 clinics volunteering to participate in the study, 15 were selected (1 dropped out later). There was an attempt to provide a geographically representative sample in Sweden, and thus the clinic effect could be included in the secondary analysis as a random effect. The study has a very well designed and executed statistical analysis plan, and I only have a few methodological comments: 1. Effect size choice: For DSHI, given that the Poisson distribution was used to test the changes, I would not necessarily use Cohen's d for describing the effect sizes for change in the count/frequency data. The Poisson model uses the log link, and assumes a very specific relationship between expected value and SD of the response counts, thus, using the SD of the response in the denominator of the Cohen's d is not the natural "normalizing" choice as it is for the "linear" models further down in Table 2. The authors are aware of the issue since they report IQRs in the rest of the manuscript for count data, so the choice of Cohen's d in Table 2 for the same outcome must be based on "comparability" arguments. However, the magnitude of expected values for both the absolute value and changes in the count/frequency are easily interpreted by any reader, so the need for a standardized effect size is less pressing then it is for psychiatric scales or biological measures. Consider replacing the Cohen's d values in Table 2 for DSHI (but not the other outcomes) with the expected count differences for each timeframe. 2. Significance levels- if the 3 differences in Table 2 are estimated from the same model with categorical time point, please include the significance of the overall test, it would be informative for a couple of the secondary outcomes that are barely significant for one timeframe. 3. Given that the reported frequency of the DSHI at the follow-up time point has many values at the lower end (at least 25% zeros based on IQR), it would be worthwhile to check the need for zero-inflated Poisson model. 4. Inclusion of random intercept/random slope was based on the likelihood ratio test. It would be good to also test a simple time-related autocorrelation structure like AR1 or the continuous time version thereof, to adjust for the longer time lag for the follow-up. 5. I would have been interested to see more exploratory tests of baseline predictors (moderators, as they are called here) of treatment effect.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Joel Paris
McGill University, Canada

1. My one criticism is that the paper does not acknowledge that there are similar methods described in the literature that have undergone clinical trials. Most particularly, Systems Training for Emotional Predictability and Problem Solving (STEPPS) is almost identical to ERGT. Unfortunately, it is not in the reference list.
It is important to know that different teams have independently developed different variations of the same approach. It is also important to acknowledge that one can take an integrative approach to BPD treatment, and avoid the “alphabet soup” of similar treatments, each with its own acronym.

Answer:
These are excellent points, and we apologize for not including Systems Training for Emotional Predictability and Problem Solving (STEPPS). We now mention STEPPS (along with DBT) as another empirically-supported treatment for BPD that targets emotion dysregulation. In addition, we now highlight that our findings, combined with evidence for the efficacy of STEPPS and DBT, illustrate the benefits of treatments that aim to promote adaptive emotion regulation in BPD, as well as provide support for emotion dysregulation as a primary mechanism underlying the pathogenesis and effective treatment of BPD and related pathology. This information is now presented in the discussion section of the revised manuscript:

Page 22: Although results of this study provide preliminary support for the utility of ERGT in routine clinical care, they also highlight more broadly the potential utility of targeting emotion dysregulation in the treatment of BPD-related pathology. Notably, there are several other empirically-supported treatments for BPD and related pathology that directly target emotion dysregulation, including DBT[6] and systems training for emotional predictability and problem solving (STEPPS;[45]). Findings of the efficacy of those treatments for BPD,[23,45,46] combined with both the results of the current study and past findings supporting the efficacy of ERGT for DSH within BPD,[11,12] highlight the potential benefits of interventions aimed at promoting adaptive emotion regulation among individuals with BPD and provide further support for emotion dysregulation as a primary mechanism underlying the pathogenesis and effective treatment of BPD and related pathology.[47]

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Reviewer: 2
Kirsten Barnicot
Imperial College London, United Kingdom

1. However, a major inaccuracy is the authors' use of the term "effectiveness trial" or "effectiveness study" to describe the research. The effectiveness of an intervention can only be determined using an RCT design with random allocation to intervention versus control groups, whereas this was an uncontrolled study evaluating change on the outcome measures pre and post-intervention. Any changes on the outcome measures cannot necessarily be attributed to the intervention and therefore the effectiveness of the intervention cannot be determined from this study. I would consider "real-world outcome study" to be a more accurate descriptor and would suggest the authors change this term throughout the paper (e.g, title, abstract, strengths + limitations, pg. 5 aims and design, discussion pg. 18 and any other places).

Answer:

Thank you for this comment. We agree that the use of the term “effectiveness trial” could be misleading. Therefore, we have now removed any mention of “effectiveness” in the manuscript when referencing our trial. Instead, we use terms such as “evaluation” and “uncontrolled open trial design.” The manuscript has been modified in the following sections:

Title: Emotion Regulation Group Therapy for Deliberate Self-Harm: A Multi-Site Evaluation in Routine Care using an Uncontrolled Open Trial Design

Abstract, Objective: In order to increase the availability of empirically supported treatments for individuals with borderline personality disorder and deliberate self-harm, an evaluation study of ERGT in routine clinical care was conducted with therapists of different professional backgrounds who had received brief intensive training in ERGT prior to trial onset.

Abstract, Design: Multi-site evaluation, using an uncontrolled open trial design with assessments at pre-treatment, post-treatment, and six-month follow-up.

Conclusions: ERGT appears to be a feasible, transportable, and effective useful treatment for deliberate self-harm and other self-destructive behaviours, emotion dysregulation, and psychiatric symptoms when delivered by clinicians in the community.

Page 3: Strengths and limitations: This multi-site effectiveness evaluation in routine clinical care study suggests that emotion regulation group therapy may be an easily disseminated and effective useful treatment for deliberate self-harm.

Page 4: Although the past two decades have seen the development of several efficacious treatments for DSH within BPD, including dialectical behaviour therapy (DBT;[6]), mentalization-based treatment,[10] , and emotion regulation group therapy (ERGT;[11,12]), few studies have evaluated examined the effectiveness of these treatments in traditional clinical settings (for exceptions, see[13-16])

Page 4: Effectiveness Trials of treatments provided in routine clinical settings, on the other hand, are designed to can evaluate how a treatment works under more real-world conditions and, as such, contribute important information about the utility and feasibility of a treatment in traditional clinical settings. These trials also play an important role in increasing the availability of evidence-based treatments.[20] Thus, further research examining the effectiveness utility of empirically supported treatments for DSH within BPD in real world clinical settings is needed.

Page 5: Specifically, in an effort to increase the availability of clinically-feasible treatments for DSH in BPD within the community, we conducted an evaluatedion the effectiveness of ERGT (a 14-week adjunctive group treatment with established efficacy in the treatment of DSH within BPD;[12]) in routine clinical care, as delivered by community clinicians at 14 psychiatric outpatient clinics throughout Sweden.

Page 5: The present effectiveness trial was conducted at 14 psychiatric outpatient clinics located throughout Sweden.

Page 19: The present multi-site evaluation of ERGT in routine clinical care provides additional support for the feasibility and transportability of ERGT this treatment.

Page 20: Results from this effectiveness trial Although the results of this study need to be interpreted with caution (due to the lack of a control group), they are similar to those obtained in previous ERGT efficacy trials,[12,13]

2. Similarly there are several instances throughout the paper (e.g. abstract, page 22, any other places) where the authors conclude that their research has shown that ERGT is an "effective" intervention. I would disagree that this conclusion can be reached on the basis of the research, for the reasons outlined above. The study has shown that individuals receiving ERGT experience significant improvements on a number of outcomes by these cannot necessarily be attributed to ERGT. I would suggest the authors change statements on effectiveness throughout to avoid over-stating their findings.

Answer:
Again, we recognize that the use of the term “effective” could be misleading. Therefore, we now no longer conclude that our study shows that ERGT is an effective intervention. Instead, we simply state that our findings suggest the “utility” and “feasibility” of ERGT in routine clinical care. We have made the following changes to the manuscript:

Abstract, Conclusions: ERGT appears to be a feasible, transportable, and effective useful treatment for deliberate self-harm and other self-destructive behaviours, emotion dysregulation, and psychiatric symptoms when delivered by clinicians in the community.

Page 3, Strengths and limitations: This multi-site effectiveness evaluation in routine clinical care study suggests that emotion regulation group therapy may be an easily disseminated and effective useful treatment for deliberate self-harm.

Page 3, Strengths and limitations: Results revealed Participants reported continued reductions in deliberate self-harm after treatment conclusion.

Page 3, Strengths and limitations: This study lacked a control group, limiting our ability to draw conclusions about the effectiveness of ERGT specifically.

Page 20: Although the results of this study need to be interpreted with caution (due to the lack of a control group), they results from this effectiveness trial are similar to those obtained in previous ERGT efficacy trials,[11,12] which have revealed positive effects of ERGT on DSH, emotion dysregulation, and psychiatric symptoms.

Page 20: These findings provide further support for the durability of improvements following this relatively brief and non-intensive treatment, suggesting that participants may experience durable gains may be obtained through ERGT even when delivered by community clinicians with only brief training in this treatment.

Page 25: Despite these limitations, our results provide further evidence for the utility and transportability of ERGT, suggesting that this is a feasible and effective treatment for DSH, emotion dysregulation, and psychiatric symptoms when delivered by community clinicians in traditional clinical settings.

3. Pg. 5 the design is described as an "open trial design". It would be helpful to clarify that this was an "uncontrolled open trial" as open trials can be either controlled or uncontrolled.

Answer:
We agree with this suggestion and now include the word “uncontrolled” when describing our trial. The following changes has been made to the manuscript with regard to this comment:

Title: Emotion Regulation Group Therapy for Deliberate Self-Harm: A Multi-Site Evaluation in Routine Care using an Uncontrolled Open Trial Design

Page 5: We used an uncontrolled open trial design with a six-month follow-up.

4. The exclusion of people with substance dependence should be justified, particularly in the context of a "real world" outcomes study, as in everyday clinical practice BPD and substance dependence are very common comorbidities, and so their exclusion may limit generalisability.

Answer:
The Reviewer brings up an important point, and we appreciate having the opportunity to justify our decision. We made this decision for a couple of reasons. First, one reason for having ongoing (past month) substance dependence as an exclusion criterion was to ensure comparability of the findings to previous ERGT trials (e.g. Gratz, et al., 2014). Further, we had ethical concerns about including individuals with ongoing substance dependence into an intensive and demanding treatment; particularly as adherence to the study protocol may have prohibited needed individual substance use-related interventions to ensure treatment compliance. We judged the risk of drop-out or “failing” in treatment would be even higher than for our standard BPD patients. Finally, in Sweden, individuals with a ongoing substance dependence would not be offered treatment within a psychiatric clinic but rather within a substance dependency treatment center. Given this, we do not believe that our decision to use this exclusion criteria negatively impacts the generalizability of our findings, at least within a Swedish psychiatric context. That said, given the high co-occurrence of substance dependence and BPD, we do acknowledge that excluding these individuals may have limited the external validity of the sample to patients with BPD as a whole. We now present our justification for this exclusion criterion and its implications in the discussion of limitations:

Page 23: Finally, current (past month) substance dependence was an exclusion criterion in this study, both to ensure comparability with previous ERGT trials and because active substance dependence requires specialized treatment and a higher level of care. Indeed, in Sweden, individuals with ongoing substance dependence are not necessarily offered treatment within a psychiatric clinic; rather, they may be referred to specialized substance dependence treatment centers. Thus, it is unlikely that the exclusion of such individuals negatively affected the generalizability of this sample to a typical Swedish psychiatric clinic. Furthermore, this criterion did not exclude individuals with past (or even recent) substance use problems. Nonetheless, given the high co-occurrence of substance dependence and BPD,[50] excluding these individuals may have limited the external validity of the sample to patients with BPD as a whole.

5. Finally, the discussion of the superior outcomes in intervention completers attributes this entirely to the intervention - the authors should also highlight that intervention completers may have differed from dropouts in ways that predisposed them to better outcomes and hence their superior outcomes may not be attributable to the intervention.

Answer:
This is an excellent point, and we now recognize that other factors may underlie treatment completion status and symptoms improvement:

Page 19: These results are consistent with past findings that characteristics of participants’ ongoing therapy in the community had minimal impact on treatment response to ERGT,[42] and suggest that it is engagement in ERGT rather than other (non-specific) treatment-related factors that influences

reductions in DSH frequency. Nonetheless, the uncontrolled open trial design precludes conclusions regarding the causal relation of treatment participation to symptom improvement, as there may be other factors underlying both treatment completion status and symptom improvement (i.e., motivation for treatment or alliance with treatment providers) that may, at least in part, account for the present findings.

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Reviewer: 3
Hanga Galfalvy
Columbia University, New York, NY, USA

1. Effect size choice: For DSHI, given that the Poisson distribution was used to test the changes, I would not necessarily use Cohen's d for describing the effect sizes for change in the count/frequency data. The Poisson model uses the log link, and assumes a very specific relationship between expected value and SD of the response counts, thus, using the SD of the response in the denominator of the Cohen's d is not the natural "normalizing" choice as it is for the "linear" models further down in Table 2. The authors are aware of the issue since they report IQRs in the rest of the manuscript for count data, so the choice of Cohen's d in Table 2 for the same outcome must be based on "comparability" arguments. However, the magnitude of expected values for both the absolute value and changes in the count/frequency are easily interpreted by any reader, so the need for a standardized effect size is less pressing then it is for psychiatric scales or biological measures. Consider replacing the Cohen's d values in Table 2 for DSHI (but not the other outcomes) with the expected count differences for each timeframe.

Answer:
We thank the reviewer for the thoughtful and relevant feedback. We have now adjusted the effect size calculation in accordance with the Reviewer's request and report absolute numbers and percent change in frequency per assessment point for the count data (self-harm or self-destructive behaviours). In order to compare our results with previous ERGT-trials, we did however, keep the reporting of Cohen's d of the log-transformed count data, but moved it to the text paragraphs of the results-section. We hope this is acceptable to the Editor and Reviewer.

Page 13: Effect sizes were calculated for changes between pre-treatment, post-treatment, and six-month follow-up. For the count variables (i.e. DSHI-frequency and BSL), the average percentage change from baseline to any subsequent time point with 95% confidence intervals was used as an effect size. This was calculated by exponentiating the estimate for the slopes derived from the negative binomial models, and interpreting the range below or above one as the percentage decrease or increase in the outcome for a one-unit increase in the predictor. Effect sizes for the remaining continuous outcomes are reported as Cohen's d, calculated by dividing the appropriate slope estimate (i.e., pre- to post-treatment: S1, pre-treatment to six-month follow-up: S1+S2, and post-treatment to six-month follow-up: S2) by the pre-treatment standard deviation.

Page 14: There was a 52% significant reduction in DSH frequency from pre- to post-treatment, and 76% reduction from pre-treatment to six-month follow-up.

Alternatively, the observed means for DSH frequency were 53.68 (SD = 99.88), 37.45 (SD = 72.22), and 28.69 (SD = 95.44) at pre-treatment, post-treatment, and follow-up, respectively. Effect sizes (Cohen's d) based on log-transformed data showed There were medium-sized significant reductions in DSH frequency and versatility from pre- to post-treatment (d = 0.52, 95% CI: 0.30, 0.75), . Moreover, results revealed further significant improvements in DSH frequency from post-treatment to

six-month follow-up (d = 0.47, 95% CI: 0.27, 0.70) . The improvements in DSH from pre-treatment to six-month follow-up were accompanied by medium (for DSH versatility) to and large (for DSH frequency) effect size reductions from pre-treamtent to six-month follow-up (d = 0.99, 95% CI: 0.70, 1.30, p < .001).

The observed medians for DSH frequency were 22.0 (IQR: 9.5-56.0), 10.0 (IQR: 2.8-45.5), and 4.0 (IQR: 0.0-13.0) at pre-treatment, post-treatment, and follow-up, respectively.

Page 15: Median reduction in self-destructive behaviours over each time period is reported in Table 2.The observed mean self-destructive behaviour scores were 4.82 (SD = 3.69) 4.0 (IQR: 2.0-7.0), 3.65 (SD = 4.24) 2.0 (IQR: 1.0-5.0) and 3.24 (SD = 3.61) 2.0 (IQR: 0.3-5.0) at pre-treatment, post-treatment, and follow-up, respectively. Analyses on log-transformed data showed small to medium effect sizes between pre- and post-treatment (Cohen's d = 0.43, 95% CI: 0.20, 0.65, p < .001) and pre- and six-month follow-up (d = 0.55, 95% CI: 0.27, 0.77, p< .001) on BSL.

2. Significance levels- if the 3 differences in Table 2 are estimated from the same model with categorical time point, please include the significance of the overall test, it would be informative for a couple of the secondary outcomes that are barely significant for one timeframe.

Answer:
The statistical significances of overall model tests (compared to null models with no fixed effects and only random intercepts) are now included in Table 2, in the column "model p". All models were significant. An explanatory note has also been added to the table foot.

Table 2, page 18: bp-value of log-likelihood ratio comparison with null model including no fixed effects and only random intercept.

3. Given that the reported frequency of the DSHI at the follow-up time point has many values at the lower end (at least 25% zeros based on IQR), it would be worthwhile to check the need for zero-inflated Poisson model.

Answer:
We appreciate this suggestion and have rerun all analyses for the count variables according to the Reviewer's suggestion. Unfortunately, when fitting the zero-inflated Poisson mixed model for the DSHI in R (package: glmmADMB) and Mplus, the model did not converge. Nonetheless since we have a related problem with overdispersion, we fitted a zero-inflated negative binomial model, which did converge. However, when comparing this model with a standard negative binomial mixed model it was not a better fit according to any model fit indices. We therefore suggest that we present the results from the simpler model, the standard negative binomial mixed model and have changed accordingly for both count outcomes (DSH frequency and BSL) throughout the text (see below). Conducting these analyses did not change our conclusions from previous submission but have led to somewhat different estimates reported in Table 2. We do believe that this new statistical model is appropriate under these circumstances but are, however, happy to consider further suggestions from the Reviewers and Editor.

Page 12: All analyses were performed in R using random effects modelling.[39] The count variables, DSH frequency and BSL, were analysed using Poisson models negative binomial generalized mixed models, and the remaining continuous outcomes were analysed using linear models.

4. Inclusion of random intercept/random slope was based on the likelihood ratio test. It would be good

to also test a simple time-related autocorrelation structure like AR1 or the continuous time version thereof, to adjust for the longer time lag for the follow-up.

Answer:
We thank the reviewer for this suggestion. Two of the models (DASS depression and DASS anxiety) were significantly improved by adding an autocorrelation structure, although estimates were marginally affected. We have added a statement about autocorrelation structure to the analysis section and revised the estimates obtained from the DASS depression and anxiety models.

Page 12: Random intercepts and random slopes as well as autoregressive correlation structures were included in the models if they significantly improved model fit according to log-likelihood ratio tests.

5. I would have been interested to see more exploratory tests of baseline predictors (moderators, as they are called here) of treatment effect.

Answer:
We appreciate this suggestion, but we believe that a comprehensive prediction analysis is beyond the scope of the present article. However, we do include several possible predictors in our sensitivity analyses that assess the integrity of the main analyses, and we hope that the Editor and Reviewer find these to be sufficient within the scope of evaluating the possible effects of implementing ERGT in routine care.

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To conclude, we would like to thank the Editor for inviting us to resubmit this manuscript and the Reviewers for their thorough reading of the manuscript and helpful and valuable comments. We believe these comments have improved the manuscript, and we hope the Editor and Reviewers agree. We appreciate the continued consideration of our manuscript for publication in BMJ Open.

VERSION 2 – REVIEW

REVIEWER	Joel Paris Professor of Psychiatry, McGill University
REVIEW RETURNED	19-Jun-2017

GENERAL COMMENTS	I am satisfied with this revision

REVIEWER	Kirsten Barnicot Imperial College London
REVIEW RETURNED	03-Jul-2017

GENERAL COMMENTS	I am satisfied that the authors have addressed the comments of the reviewers and that this has improved the paper.

REVIEWER	Hanga Galfalvy

	Columbia University, New York, NY, USA
REVIEW RETURNED	07-Jul-2017

GENERAL COMMENTS	My concerns were answered satisfactorily. I have no further suggestions.